# **Curriculum Vitae**

Patrick F. Coleman 17211 77th Ave. West Edmonds WA 98026 (425) 498-1722 (W) (206) 775-1687

#### Education:

B.S. Biochemistry, Washington State University, Pullman WA; With Highest Honors, 1970.

**Ph.D. Chemistry (Biochemistry)**, Stanford University, Stanford CA, 1974. Thesis Advisor: Professor Harden M. McConnell.

National Institutes of Health Postdoctoral Fellow in Biochemistry/Molecular Biology, Stanford University School of Medicine, Stanford CA, 1974-1976. Advisor Professor George R. Stark.

**Giannini Foundation Fellow**, Biochemistry/Molecular Biology, Department of Biochemistry, Stanford University School of Medicine, Stanford CA, 1976-1977, with Professor Stark.

### **Experience:**

### Bio-Rad Laboratories

1999-Present: Manager, Biologics R&D and Manufacturing — Provide leadership for more than 5 senior scientists and 25 Biologics Manufacturing and Quallity Control staff. Resonsibilities include the design and manufacture of a wide array of biomolecules used in several immunoassay platforms. The design aspects include sequence determinations for synthetic peptides and recombinant proteins that can be expressed in bacterial, or mammalian host cell systems. The designs for conjugated biomolecules and immunoassay reporter molecules are also developed. Process designs for the production of the selected biomolecules are developed and transferred into the Manufacturing environment. Many of the developed biologics are used in blood screening tests, which are subject to FDA licensing requirements. Other developed biomolecules are used in the reagents supporting the Bio-Rad BioPlex 2200 mulltiplex immunoassay system. Certain areas in the Manufacturing environment are also subject to FDA licensing requirements. Resposibilities include the production of large quantities of cultivated HIV-1 and HIV-2 viruses, and the high volume production of HIV-1 Western blot pages. The Bio-Rad HIV-1 Western Blot commands about 90% of the US WB market.

# Sanofi Diagnostics Pasteur (SDP)/Genetic Systems (GS)-Redmond WA:

1992- 1999: Director, Research and Development -- Provide leadership for 10 scientists developing highly sensitive and specific antibody detection immunoassays, for transmissible blood viruses, using novel chemisynthetic peptides and recombinant proteins. The assays employ several state-of-the art immunochemical formats and they are on the PLA/ELA regulatory track with the FDA. The strict regulatory environment insures extremely well-designed and developed, tightly controlled processes that are executed in a well-engineered and audited GMP manufacturing environment. Other responsibilities include: 1.) Active participation on the Genetic Systems Operating Committee, which manages all facets of the day to day business at GS; 2.) Managing an annual R&D budget of \$1 MM, 3.) Providing technical leadership for the peptide chemistry technology base and recombinant protein development 4.) Maintaining a peptide/recombinant technology "Center of Excellence" for SDP (established over an 8 year period); 5.) Managing the team that delivered the

second generation EIA for HIV-1/HIV-2, based on synthetic peptides, which received FDA approval August, 1997, 6.) Managing the provision of research scale and manufacturing scale synthetic peptide and recombinant biologicals to all SDP worldwide affiliates 7.) Securing proposal-based annual funding from Elf-Aquitaine for foreign scientists to perform basic research in our laboratories. and 8.) Acting as Technical Director for the Washington State licensed, Genetic Systems Clinical Reference Laboratory.

1987-1992: Sr. Program Manager, Research and Development- Managed several teams of scientists responsible for developing novel synthetic peptides that have been incorporated into a wide variety of highly sensitive and specific immunoassays used in the detection of blood viruses (i.e.HIV-1, HIV-2, HTLV-I, HTLV-II and HCV). The novel peptide chemistry allows for optimum presentation of the immunodominant viral epitopes represented by the peptides. Led the team that developed the rapid test GENIE HIV-1/HIV-2, which is currently manufactured in France for sale outside the U.S., under the name MultiSpot™. Led the development of microplate ELISAs, using synthetic peptides, for HTLV-I/II and HCV. Responsible for R&D budget. Laid the foundation (scientific staff, laboratories, equipment) for what would become the SDP Peptide/Recombinant "Center of Excellence". Biologicals developed at "Center" have been incorporated in most SDP blood virus assays worldwide.

1986-1987: Manager, Human Diagnostics, Synbiotics Corp., San Diego CA- Established the Human Diagnostics group comprised of 6 immunoassay development scientists. Designed and developed an immunoconcentration device with a "+/- readout. Direct antigen capture assays, incorporating mono- and polyclonal antibodies, were developed in the 5 minute rapid format. These included assays for C. trachomatis, Strep A and HCG. A novel micro well assay for C. trachomatis LPS was also developed

## Beckman Instruments, Carlsbad CA:

1984-1986: Chief Development Chemist- Technical Leader for Clinical Chemistry product line. Managed a team of 14 scientists and 5 Manufacturing Technicians in the development and pilot production of bead-based ELISAs and clinical chemistry reagents. Immunoassays for Human prolactin , ferritin, cortisol and pancreatic lipase using mono- and polyclonal antibodies were developed. Several very specific, high affinity monoclonal antibodies were cloned. Critical improvements were made in the EPSILON TSH and Digoxin bead assays to keep them on the market. Assumed responsibility for manufacturing and QA/QC for all Beckman Epsilon kits. Managed product improvements and production support for several different reagent lines, including dry powder and stable, liquid-based reagent formulations.

1983-84: Principal Development Chemistresponsible for developing new clinical chemistry reagents and for maintaining the existing line of dry
powder and liquid clinical chemistry reagents. New products included a high performance rate
cholesterol reagent kit, that was later adapted to the Beckman Astra System and an enzymatic total
bilirubin reagent kit. Line maintenance included the dry powder product line leader Amylase DS as
well as all other dry powder and liquid reagent kits.

1979-1983: Group Leader, Clinical Chemistry, Calbiochem-Behring Corp., La Jolla CA-Managed a team of 9 scientists responsible for the development of clinical chemistry reagent kits for the domestic and European markets. Also managed the Applications Group responsible for the application of the reagent kits to a variety of automated chemistry analyzers. Reagent development menu included the standard blood chemistries, but also include pancreatic amylase and lipase. Played a key role in integrating the biochemicals R&D scientists into the new product development process.

1978-1979: Associate Director, Research and Development, ECS Division, Bio-Rad Laboratories, Anaheim, CA- Managed a team of 5-7 Scientists responsible for the R&D for human serum based laboratory control products and for clinical chemistry test kits. The control products consisted of a multi-level Total Chemistry panel, RIA Total Ligand, CEA, Elevated Lipid and Urine

controls. The reagents consisted of Total and HDL Cholesterol, Triglycerides, Glucose and CPK. Developed manufacturing and QA/QC documentation for the above products. Established a stability assessment program for the product development process. Established a value assignment program for the multiconstituent control products.

1977-1978: Research Scientist, Hyland Laboratories, Costa Mesa, CA- Managed 8 scientists in the R&D for clinical chemistry laboratory control products. Included were Blood Gas, Multi-constituent serum-based, and Therapeutic Drug controls. Developed a novel serum/plasma base matrix and spray freezing process for manufacturing lyophilized control products.

1977: Consultant, Peter M. Dollinger Associates, Menlo Park, CA- Researched and prepared detailed summaries and analyses of the known biological fate and environmental impact of two widely used pesticides in the State of California, Endosulfan and Methomyl. The documents were used by State legislators to draft regulations governing the use of these and other pesticides in the State of California.

1974-1977: Postdoctoral Fellow, Stanford University Medical School, Stanford CA- Conducted studies on the regulation of gene expression in a mammalian cell line in tissue culture. Investigated and elucidated the primary mechanisms controlling the induced overproduction of an essential metabolic enzyme complex (de novo pyrimidine biosynthesis) in an SV40-transformed hamster cell line. Published reports elucidated several important mechanisms operating at the gene level and the protein synthesis level for regulating the cellular overproduction of the fused-enzyme complex.

1970-1974: Doctoral Student, Stanford University, Stanford, CA- Investigated the use of a solution-stable, nitroxide free radical labeled analog ("spin label") of 2,3-DPG to study allosteric equilibria, established in solution, as a function of oxygen binding in normal and abnormal human hemoglobins (Hb). The allosteric binding of the spin label was measured as a function of heme saturation. The data was fit to a computer-based modified MWC two-state model for cooperative oxygen binding to hemoglobin. The model was generalized to account for the oxygen saturation curves for HbA and a large number of abnormal hemoglobins. Work included the complex organic chemical synthesis of several biologically active, spin labeled compounds and performance of technically rigorous, Hb/oxygen binding curve experiments where EPR and UV data were collected simultaneously.

1968-1970: Predoctoral Research Fellow, Washington State University, Pullman, WA- In the laboratory of Prof. J.I.Legg, synthesized and performed the structural determination by NMR of several novel, chiral cobalt(III) chelate systems. Additional work included the synthesis of a cobalt(III) chelate using a symmetrical tridentate ligand (triaminocyclohexane) which has the capability for the N-terminal hydrolysis of Glu, Asp or Cys from a polypeptide. A proposal to use this and related chelates along with ion exchange chromatography to sequence polypeptides received the 1969 NW Chapter ACS Young Investigator Award.

## Teaching Experience:

<u>1970-1974: Stanford University-</u> Awarded Teaching Assistantships in Quantitative Analysis, Organic Synthesis, Biochemistry and Physical Chemistry.

<u>1968-70: Washington State University-</u> Awarded a Teaching Assistantship in Honors Level Quantitative Analysis.

## Personal:

Born: September 27, 1948, Yakima WA.

Patents:

5,215,885 - "Stable Two-Part Chromogen Solution"; 5,439,792 - Cysteine Thiol-protected Peptides for Use in Immunoassays (issued also in Australia, Patent No. 652,919); several patent applications pending in several countries.

# **Publications:**

Provided upon request.

## References:

Provided upon request.